REMARKS

Applicants thank Examiner Wang for his time and consideration of the present application during the telephonic interview of December 4, 2009 with the undersigned.

During the interview, an amendment to independent claim 34 was proposed to further distinguish the claimed invention from the cited documents. In particular, the proposed amendment included language to emphasize that the claimed colloidal solution of metal particles or metal compound particles is formed from one metal. Examiner Wang noted that DE 19803891 discloses the formation of single metal containing solution, albeit as an intermediate, in the Examples.

The undersigned inquired as to whether such an amendment would raise new issues, and, thus, require further consideration and/or search. The Examiner stated that he would have to update the search if the claims were amended.

Accordingly, this application is amended in a manner to place it in condition for allowance at the time of the next Official Action. As the Amendment is expected to require further consideration and/or search, a Request for Continued Examination is being filed with this amendment.

Status of the Claims

Claim 34 is amended. Support for the amendment to claim 34 may be found, for example, at paragraph [0014] and the Examples which include one metal.

Claim 36 was corrected for a formal matter.

Claims 34-36, 38, and 54-64 remain in this application.

Claim Rejections-35 USC §102

Claims 34-36 and 38 were rejected under 35 U.S.C. §102(b) as being anticipated by KATSUHIRO et al. JP 2002-180110 ("KATSUHIRO"). This rejection is respectfully traversed for the reasons below.

The claimed invention is directed to a colloid solution of metal particles or metal compound particles for use in an integrity test for a virus membrane, the method of particles and the method of using the particles in the integrity test. Unless the colloid solution of the metal particles or metal compound particles is stable for an extended period of time, the colloid solution of the present invention is not able to be used in an integrity test after long storage. Moreover, to be stable under broad range of pH is also an important performance which the present colloid solution to be used under a variety of conditions should possess.

The amendment to independent claim 34 defines the claimed invention as a colloid solution of metal particles or

metal compound particles being formed from one metal used in an integrity test for a virus removal membrane. This colloid solution comprises from 0.0001 to 0.1 wt% of metal particles or metal compound particles, wherein all of these metal particles or metal compound particles of the colloid solution are formed from one metal and have an average particle size diameter of 15-40 nm.

That is, the metal particles or metal compound particles of the colloid solution recited in the preamble of claim 34 have the following characteristics:

- they are formed from one metal;
- they are present in an amount from 0.0001 to 0.1 wt%; and
- they have an average particle size diameter of 15-40 nm.

Accordingly, the claimed invention differs from the colloid solution of KATSUHIRO which is formed from at least more than one metal.

Therefore, the claimed invention is novel over KATSUHIRO, and withdrawal of the rejection is respectfully requested.

Claim Rejections-35 USC §102/103

Claims 34, 36 and 38 were rejected under 35 U.S.C. §102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as obvious over DUFF et al. (GOLDEN et al. as noted in the Official Action) DE 19803891 ("DUFF"). This rejection is respectfully traversed for the reasons below.

The colloid solution disclosed in DUFF is for catalytic use, and thus, it neither requires nor possesses long-term colloidal stability or properties as claimed.

Moreover, DUFF fails to disclose or suggest a solution comprising "surfactant and/or chelating agent" as recited in independent claim 34.

Furthermore, while DUFF may suggest forming an intermediate one metal-containing solution in order to prepare the final composition of the Examples, this intermediate solution is not shown to include metal particles or metal compound particles in an amount from 0.0001 to 0.1 wt% with an average particle size diameter of 15-40 nm. Also, while DUFF may suggest a range of colloid particle sizes that overlap the claimed average particle sizes, the final composition does not include one metal in the form of metal particles or metal compound particles in an amount from 0.0001 to 0.1 wt%. Accordingly, neither the intermediate solution nor the final composition of DUFF suggests the claimed composition.

Due to these differences, claim 34 is novel over DUFF.

Furthermore, with respect to method claims, DUFF produces the colloid solution by adding dispersant to dissolved metal compound solution and then reducing it. As defined by "the method for producing a colloid solution" recited in Claim 38, the present invention produces the colloid solution via causing the metal particles (or the metal compound particles) to be formed by

reducing the metal compound, then adding a dispersant and further adding an surfactant and/or a chelating agent.

Thus, the claimed invention and DUFF differ in the method for providing stability to a colloid solution.

Indeed, as evidenced by Comparative Example 9, the colloid solution produced via DUFF's method (i.e. adding dispersant to dissolved metal compound solution and then reducing) was not homogenous, and the colloid solution failed to show long-term stability like the present invention (unstable compare to the present invention).

This result confirms that the colloid solution of the present invention and DUFF are not identical. Due to changing dissolved metal compound solution into metal particles by reduction reaction after the addition of dispersant, the colloid obtained by DUFF's method shows insufficient stability. Accordingly, the storage stability of the resulting colloid solution in DUFF is far from storage stability parameter of the present invention.

As mentioned above, DUFF's colloid solution is for catalytic use. Due to differences in the performance between the present invention and DUFF caused by the use difference, DUFF's colloid solution does not need to be stable for long a term and in a broad Ph range to be formed from composition necessary for such stability. As a result, DUFF's method for producing a

colloid solution does not utilize a method necessary for providing such stability to the colloid solution.

Therefore, DUFF fails to disclose or suggest the claimed properties, surfactant and/or chelating agent, or method steps of the present invention, and withdrawal of the rejection is respectfully requested.

Claim Rejections-35 USC §103

Claims 54 and 56-61 were rejected under 35 U.S.C. §103(a) as being unpatentable over MELTZER et al. ("MELTZER") in view of KATSUHIRO. Claim 64 was rejected under 35 U.S.C. §103(a) as being unpatentable over MELTZER in view of KATSUHIRO, further in view of CAUSSERAND et al. ("CAUSSERAND").

These rejections are respectfully traversed for the reasons that follow.

MELTZER discloses that the integrity of a virus removal membrane is measured by a particle challenge test using dextran, PVP or colloidal gold. The Official Action had acknowledged that MELTZER is silent regarding a washing step and the components of the gold colloid solution.

The Official Action offered KATSUHIRO for teaching a composition of the gold colloid solution, but as discussed above relative to the anticipation rejection KATSURHIRO fails to disclose or suggest the claimed colloidal solution from claim 34.

KATSUHIRO also fails to disclose or suggest that the colloid solution would have been suitable for an integrity test for a virus membrane. KATSUHIRO merely discloses using a colloid solution as catalysts. There is no discussion about the reduction in interaction between membrane materials, or guidance for using the metal colloid solution as a standard material for examining the permeability of a membrane in an integrity test for the membrane.

Indeed, in order to be suitable in an integrity test for a virus membrane, the properties of each colloidal metal particle, such as the condition of the surface, i.e., smoothness and affinity to a membrane of the surface should be homogeneous and of the same quality. And, such a metal colloid solution should be formed from only one type of metal.

However, KATSUHIRO teaches that the colloid solution secures its stability by being formed from not less than two metals. Thus, the colloid solution taught in KATSUHIRO cannot be formed from one metal as in the case of the present invention.

Moreover, if the colloid solution taught in KATSUHIRO were used in an integrity test for a virus membrane, it would have been difficult to conduct complete integrity test. This is due to the existence of metals which have different properties in the colloid solution. For example, one who would have conducted the test may have tried to confirm integrity (completeness) of pore size, but it would have been difficult to do so, since

different metal particles would have been buried in different pores.

In view of the above, the present claimed invention is different from the invention disclosed in KATSUHIRO. And, due to the difference, it is clear that performance necessary for a colloid solution to be used in an integrity test for a virus membrane as in the case of the present invention cannot be obtained by KATSUHIRO.

Thus, the shortcomings of MELTZER for reference purposes cannot be remedied by KATSUHIRO.

CAUSSERAND was offered for teaching a washing step after the filtration step using an alkali solution. However, CAUSSERAND fails to remedy the shortcomings of MELTZER and KATSUHIRO for reference purposes.

Therefore, withdrawal of the rejection of claims 54, 56-61 and 64 is respectfully requested.

Claims 55 and 62-63 were rejected under 35 U.S.C. §103(a) as being unpatentable over TATEISHI et al. 2001 ("TATEISHI") in view of NAOKI et al. JP 2002-060805 ("NAOKI"). This rejection is respectfully traversed for the reasons below.

TATEISHI was offered for teaching an integrity test which uses a colloid solution. However, TATEISHI is silent in teaching the claimed colloid solution according to claim 34.

NAOKI fails to render this shortcoming of TATEISHI for reference purposes, as NAOKI requires not less than two metals, similar to KATSUHIRO.

Thus, as the combination fails to teach the claimed colloid solution required in claims 55, 62 and 63, the combination fails to render obvious the claimed invention.

Therefore, withdrawal of the rejection is respectfully requested.

Conclusion

In summary, KATSUHIRO, NAOKI and DUFF fail to disclose the claimed colloid solution, and, in fact, teach away from one metal. Accordingly, these solutions cannot have the same properties as those claimed. As to the integrity test using such a colloid solution, while MELTZER and TATEISHI were offered for teaching such a test, these documents also fail to disclose or suggest using such a colloid solution

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

/Robert A. Madsen/
Robert A. Madsen, Reg. No. 58,543
Customer No. 00466
209 Madison Street, Suite 500
Alexandria, VA 22314
Telephone (703) 521-2297
Telefax (703) 685-0573

RAM/lrs